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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,602	06/30/2000	Matthew Joseph Doyle	8141	8543
27752	7590	07/18/2006	EXAMINER	
THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL BUSINESS CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1655	
DATE MAILED: 07/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/607,602	Applicant(s) DOYLE ET AL.	
	Examiner Ralph Gitomer	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 7 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment and RCE Request received 5/24/06 have been entered and claims 2-4, 7 are currently pending in this application.

This application received a decision from the Board of Patent Appeals and Interferences on 3/31/06 which affirmed that whole body health benefits are inherent in the claimed method where newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. As such, the claimed method would inherently result in whole body health, even if that effect was not recognized. The claims have been newly amended to more clearly recite treating systemic disease in general as related to pathogens in the oral cavity. The relationship between periodontitis and related inflammation and tooth loss to whole body health is discussed in detail the present specification and is not new.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Pan and Singer.

Pan (WO 97/16159) teaches H2 antagonists including cimetidine may be employed in an oral composition in an amount effective to treat or prevent inflammation in the oral cavity and may also comprise essential oils to act as antimicrobial agents.

Singer (5,364,616) teaches a method for treating or preventing periodontitis comprising topically administering a composition of H₂ antagonist in the form of a dentifrice, mouthwash, mouth rinse, mouth spray or dental treatment solution. The compositions may be in the form of a toothpaste, tooth gel, powder, chewing gum and may act as odor masking agents, see column 15 lines 24-60 and claims 9-15. Various forms of the composition are discussed. Additional antimicrobial/antiplaque agents may be included.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Tsujita.

Tsujita (JP 04089428), English translation ordered but not yet available, teaches in the abstract a method of treating the oral cavity disease of gingivitis with cimetidine as an active ingredient.

Applicants are claiming a new benefit, whole body health, from an old method, administering to the oral cavity an antimicrobial agent with an H₂ antagonist. This benefit may be based on the concept of infection causing inflammation which then through cytokine and other inflammatory cascades, induces a tendency towards inflammation at distant sites. This relationship is old.

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Applicant's arguments filed 5/24/06 have been fully considered but they are not persuasive.

Applicants argue that the claims have been amended to recite the H2 antagonist is present in an amount effective to mediate systemic host reaction to the presence of periodontal pathogens in the subject's oral cavity and to reduce risk factors for systemic disease. There is no evidence submitted that the references teach the claimed method would inherently result in whole body health.

It is the examiner's position that a known method to treat periodontal disease would inherently treat whole body health.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 2 "said pathogens" lacks antecedent basis. Dependent claims should begin with a definite article.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Doyle (6,846,478) is directed to administering chlorite.

Doyle (US 2003/0206874 A1) teaches administering stannous ions.

Doyle (US 2005/0163727 A1) teaches administering antimicrobial agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ralph Gitomer
Primary Examiner
Art Unit 1655

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GROUP 1200